

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

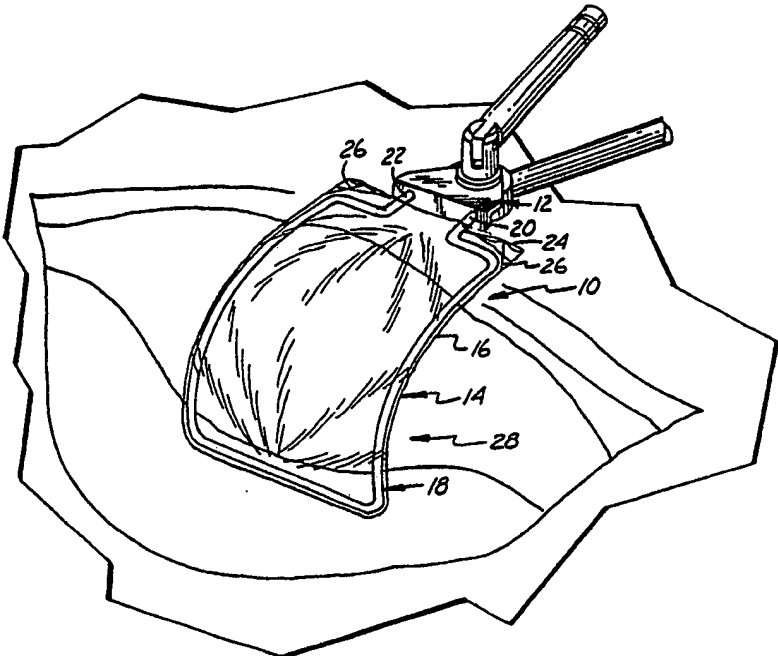
- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁴ : A61B 17/02	A1	(11) International Publication Number: WO 89/ 04145 (43) International Publication Date: 18 May 1989 (18.05.89)
(21) International Application Number: PCT/US88/03242 (22) International Filing Date: 20 September 1988 (20.09.88) (31) Priority Application Number: 118,477 (32) Priority Date: 9 November 1987 (09.11.87) (33) Priority Country: US (71) Applicant: MINNESOTA SCIENTIFIC, INC. [US/US]; 3839 Chandler Drive Northeast, Minneapolis, MN 55421 (US). (72) Inventor: LEVAHN, Bruce, A. ; 2317, Fifth Street Northwest, New Brighton, MN 55112 (US). (74) Agents: SAWICKI, Z., Peter et al.; Kinney & Lange, 625 Fourth Avenue South, Suite 1500, Minneapolis, MN 55415-1659 (US).		(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, KP, LU (European patent), NL (European patent), SE (European patent). Published <i>With international search report.</i>
(54) Title: FLEXIBLE RETRACTOR  (57) Abstract A retractor apparatus (10) includes a retractor blade (14) having a malleable element (18) that defines a blade perimeter and a retractor area. A flexible member (16) is supported by the malleable element (18) and extends over the retractor area.		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	ML	Mali
AU	Australia	GA	Gabon	MR	Mauritania
BB	Barbados	GB	United Kingdom	MW	Malawi
BE	Belgium	HU	Hungary	NL	Netherlands
BG	Bulgaria	IT	Italy	NO	Norway
BJ	Benin	JP	Japan	RO	Romania
BR	Brazil	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	LI	Liechtenstein	SN	Senegal
CH	Switzerland	LK	Sri Lanka	SU	Soviet Union
CM	Cameroon	LU	Luxembourg	TD	Chad
DE	Germany, Federal Republic of	MC	Monaco	TG	Togo
DK	Denmark	MG	Madagascar	US	United States of America
FI	Finland				

FLEXIBLE RETRACTORBACKGROUND OF THE INVENTION1. Field of the Invention.

The present invention relates to surgical retractor apparatus, and in particular, it relates to a retractor used to retract organs.

2. Description of the Prior Art.

Surgical retractors are customarily used during major surgery to hold back the incision area to expose the area in which the surgeon operates. Abdominal surgery presents particular problems because of the presence of large soft organs, especially long lengths of intestines. The positioning during surgery of these lengths of intestines is vitally important to the success of the surgery. The intestines can obscure the surgeon's vision if the intestines are not held back by retractors. On the other hand, the intestines themselves are fragile and puncture results in contamination of the field of surgery greatly increasing the risk of post-operative infection.

In the prior art, surgical absorbent clothes or sponges, sometimes with the addition of hard metal retractors, have been used to hold and separate the intestines from the point of surgery.

The Rudie U.S. Patent 3,372,696 describes the use of an abdominal pad having a flexible body member having a slight degree of rigidity with a weighted pocket formed at one end for holding back the intestines.

The Kohlmann U.S. Patent 3,749,088 describes a retractor having a blade with a lower flexible end portion.

The Hurson U.S. Patent 4,048,987 describes a hand-shaped retractor with a wire core having a multi-member body portion and a handle portion. The members of the body portion are individually adjustable.

The James U.S. Patent 3,467,079 describes a retractor having a shaft that ends in a hook and a winged blade.

The Kadavy U.S. Patent 1,947,649 describes a surgical instrument having a pair of pivotally connected members having a pair of outwardly extending arms that are inserted into a rubber covering. The arms are extended outwardly so that the covering is held taut between the two arms.

The Sinnreich U.S. Patent 4,190,042 describes a flexible retractor having a bifurcated member with a flexible membrane tensed between segments of the bifurcated member.

The LeVahn U.S. Patent 4,355,631 illustrates conventional retractors.

SUMMARY OF THE INVENTION

A retractor apparatus includes a retractor blade having a malleable element that defines a blade perimeter and a retractor area. A flexible member is supported by the malleable element and extends over the retractor area.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of the retractor apparatus of the present invention, in its position of use, the retractor apparatus being supported by a retractor support;

-3-

Figure 2 is a perspective view of the support member of the retractor device of the present invention; and

Figure 3 is a perspective view of the retractor apparatus of the present invention in a flat state.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the drawings, like reference characters will be used to indicate like elements throughout the several views. A retractor device of the present invention is generally indicated at 10 in Figure 1. The retractor 10 includes a blade 14 attached to a support member 12. The blade 14 includes a transparent membrane 16 supported by a wire element 18 in the form of a continuous loop. The wire element 18 has first and second ends 20 and 22 that are attached to the support member 12. Although the wire element 18 is shown in substantially rectangular form, the wire element may take various other shapes and be within the scope of the invention.

In the embodiment illustrated, the transparent membrane 16 is in the form of a bag having an open end 24. The wire element 18 is disposed within the bag forming the blade 14. The wire element 18 is inserted into the open end 24 and the open end 24 is heat sealed along the lines indicated by reference character 26. Alternatively, the membrane 16 need not be in the form of a bag. The membrane 16 may be a single layered membrane that is fixedly attached to the wire element 18. Preferred materials for the membrane 18 include polymeric films. A suitable polymeric film is polyethylene.

-4-

Preferably, the membrane 16 is slack, as illustrated in Figure 1. By slack is meant that the membrane forms a slight pouch or an indentation in which an organ 28 is retained. For example, the retractor device of the present invention is used to retain the bowel during deep abdominal surgery. Unlike retraction of muscle, soft tissue retraction, such as the bowel, presents a unique problem. Not only must the organ be held securely out of the way during surgery, the organ must be held in as gentle a manner as possible so that it is not damaged and circulation through the organ is not affected. The membrane provides a flexible surface, and, in the membrane's relatively slack state, an indentation or pouch is formed when the retractor is placed against the organ 28. Using the device of the present invention, the organ is gently but securely held in place, minimizing the chance of the organ sliding parallel to the retractor blade surface and out of a "retained" position. Although preferably the membrane 16 is in a slack state, the membrane could be taut, that is, held under tension, and still provide adequate retraction. In such a case, the flexibility of the film provides a retraction surface that gently retains the organ.

In addition, the membrane 18 is preferably transparent so that the organ 28 is viewable through the membrane 16. By transparent is meant that the organ is sufficiently viewable so that the condition of the organ can be ascertained. For example, lack of circulation may be indicated by a discoloration of

the organ. Such discoloration should be visible through the membrane.

To further aid in holding the organ, the wire element 18 is made of a malleable material. By malleable is meant that the wire element is bendable and then stays bent in the selected shape or form in which it is bent. As illustrated in Figure 3, the blade of the retractor device of the present invention is initially in a flat state. The surgeon then bends the wire element to form the blade to a selected shape. It will be appreciated that each surgical procedure can be different and that the capability to form the retractor to a desired shape to the needs of a particular situation is highly desirable.

In the working embodiment illustrated in the figures, the wire element is made of stainless steel and can be sterilized for repetitive use. In an alternative embodiment, the wire element may be made of metal other than stainless steel and then coated. For example, the wire element, along with the support member 12, are encased entirely in a polymeric resin, such as polyvinyl chloride or an epoxy resin. In addition, a foamed resin coating may be applied to the wire element. Coating the wire element and the support member 12 in a plastic resin permits usage of material much less expensive than stainless steel, making the device of the present invention a disposable item.

The support member 12 is made of flat sheet metal and has a main portion 30 and secondary portion 32 disposed at approximately a right angle to the

main portion 30. The portion 32 includes apertures 34 and 36 through which extend the ends 20 and 22 of the wire element 18. The apertures 34 and 36 are located adjacent the main portion 30 such that the ends 20 and 22 can be fixedly attached to the portion 30 by welding.

The support member 12 further includes an aperture 38. The aperture 38 permits attachment of the retractor device 10 to a retractor support clamp 40, as illustrated in Figure 1. The retractor support clamp is then held by a suitable retractor support, such as illustrated and described in the LeVahn et al U.S. Patent 4,617,916, assigned to the same assignee as the present application, and herein incorporated by reference. Although the specific retractor apparatus in the LeVahn et al Patent is mentioned, any suitable retractor support can be used with the retractor device of the present invention.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. A retractor apparatus for use with a retractor support and having means for attaching the retractor device to the retractor support, the device comprising:

a retractor blade including a bendable wire support member defining a blade perimeter and a retractor area, and a flexible member supported by the wire member and extending over the retractor area such that the shape of the blade is changeable.

2. The device of claim 1 wherein the membrane is substantially transparent.

3. The device of claim 2 wherein the membrane is made of a flexible polymeric material.

4. The device of claim 1 wherein the membrane is in a slack state.

5. The device of claim 4 wherein the membrane is in a sufficiently slack state to form a pouch.

6. The device of claim 1 wherein the wire member is made of a malleable material.

7. A retractor device for use with a retractor support apparatus and having means for attachment to the retractor support apparatus, the device comprising:

-8-

a retractor blade having a flexible pouch portion for engaging an organ.

9. The device of claim 8 wherein the flexible pouch portion is made of a polymeric film.

10. The device of claim 9 wherein the film is substantially transparent.

11. The device of claim 10 wherein the pouch portion has a perimeter defined by a malleable element, the malleable element being bendable to a selected shape.

12. The device of claim 11 wherein the malleable element is a wire.

13. A retractor device for use with a retractor support and having means for attachment to the retractor support, the device comprising:

- a retractor blade including a malleable element defining a perimeter of the retractor blade and defining a retractor area within the perimeter; and

- a flexible membrane extending over the retractor area and attached to the malleable element, the malleable element being bendable to a selected shape.

14. The device of claim 13 wherein the membrane is in a slack state.

-9-

15. The device of claim 13 wherein the membrane is in a taut state.

16. The device of claim 13 wherein the membrane is a polymeric film.

17. The device of claim 13 wherein the malleable element is a wire.

18. The device of claim 13 wherein the malleable element is a continuous loop.

19. A retractor device for use with a retractor support apparatus and having means for attachment to the retractor support apparatus, the device comprising:

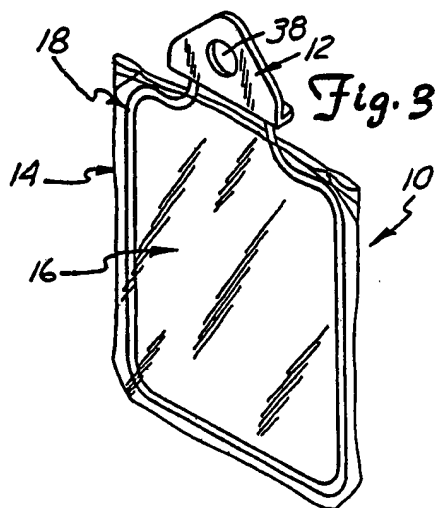
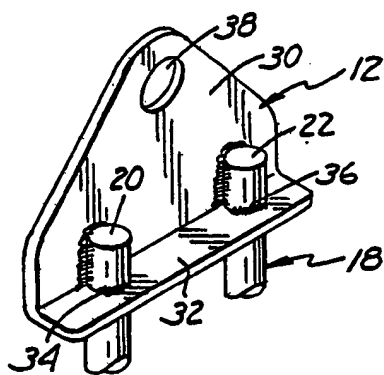
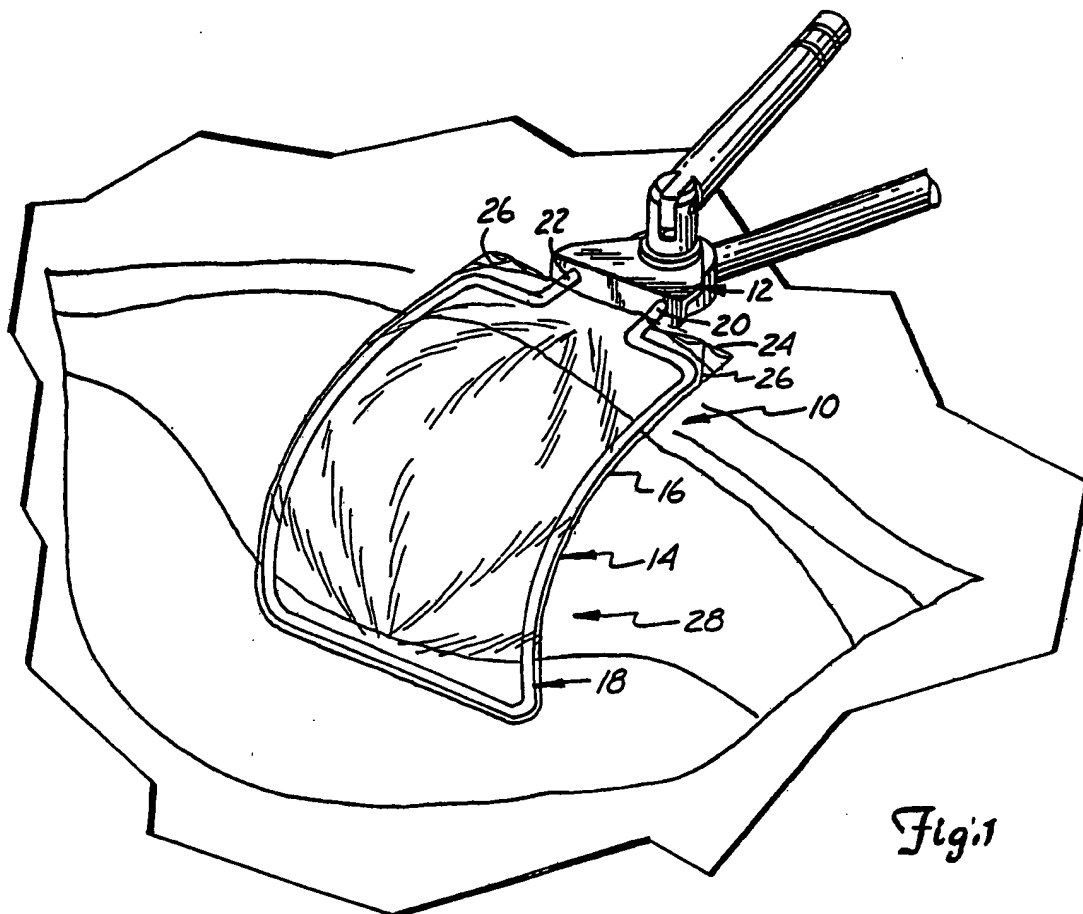
a retractor blade having a support member defining a perimeter and a retractor area and a flexible membrane attached to the support member and extending over the retractor area in a slack state.

20. The device of claim 19 wherein the membrane is made of a polymeric film.

21. The device of claim 19 wherein the membrane is substantially transparent.

22. The device of claim 19 wherein the support member is made of a malleable material such that the blade is bendable to a selected shape.

1/1



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US88/03242

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC IPC(4): A61B 17/02 U.S. Cl. 128/20																	
II. FIELDS SEARCHED <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">Minimum Documentation Searched ⁷</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; border-bottom: 1px solid black;">Classification System</td> <td style="border-bottom: 1px solid black;">Classification Symbols</td> </tr> <tr> <td style="height: 40px; vertical-align: bottom; border: 1px solid black;">U.S.</td> <td style="height: 40px; vertical-align: bottom; border: 1px solid black;">128/20</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">Documentation Searched other than Minimum Documentation to the extent that such Documents are Included in the Fields Searched ⁸</div>			Classification System	Classification Symbols	U.S.	128/20											
Classification System	Classification Symbols																
U.S.	128/20																
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">Category ¹⁰</th> <th style="width: 60%;">Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²</th> <th style="width: 30%;">Relevant to Claim No. ¹³</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; vertical-align: top;">X Y</td> <td>US,A, 3,522,800 (LESSER) 04 August 1970 See the entire document, particularly column 1, lines 42-47.</td> <td style="text-align: center; vertical-align: top;">1-7,9-17, 19-21 18</td> </tr> <tr> <td style="text-align: center; vertical-align: top;">A</td> <td>DE,A, 2,730,164 (YAMAMOTO) 08 August 1978 See Abstract, Fig. 1.</td> <td style="text-align: center; vertical-align: top;">18</td> </tr> <tr> <td style="text-align: center; vertical-align: top;">A</td> <td>US,A, 4,190,042, (SINNREICH) 26 February 1980 See Fig. 2.</td> <td style="text-align: center; vertical-align: top;">1-7,9-21</td> </tr> <tr> <td style="text-align: center; vertical-align: top;">A</td> <td>US,A, 1 947,649, (KADAVY) 20 February 1934 See Fig. 1.</td> <td style="text-align: center; vertical-align: top;">1-7,9-21</td> </tr> </tbody> </table>			Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³	X Y	US,A, 3,522,800 (LESSER) 04 August 1970 See the entire document, particularly column 1, lines 42-47.	1-7,9-17, 19-21 18	A	DE,A, 2,730,164 (YAMAMOTO) 08 August 1978 See Abstract, Fig. 1.	18	A	US,A, 4,190,042, (SINNREICH) 26 February 1980 See Fig. 2.	1-7,9-21	A	US,A, 1 947,649, (KADAVY) 20 February 1934 See Fig. 1.	1-7,9-21
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³															
X Y	US,A, 3,522,800 (LESSER) 04 August 1970 See the entire document, particularly column 1, lines 42-47.	1-7,9-17, 19-21 18															
A	DE,A, 2,730,164 (YAMAMOTO) 08 August 1978 See Abstract, Fig. 1.	18															
A	US,A, 4,190,042, (SINNREICH) 26 February 1980 See Fig. 2.	1-7,9-21															
A	US,A, 1 947,649, (KADAVY) 20 February 1934 See Fig. 1.	1-7,9-21															
<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 48%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>																	
IV. CERTIFICATION <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; border-bottom: 1px solid black;">Date of the Actual Completion of the International Search</td> <td style="width: 50%; border-bottom: 1px solid black;">Date of Mailing of this International Search Report</td> </tr> <tr> <td style="border-bottom: 1px solid black;">15 November 1988</td> <td style="text-align: center; border-bottom: 1px solid black;">03 FEB 1989</td> </tr> <tr> <td style="border-bottom: 1px solid black;">International Searching Authority</td> <td style="border-bottom: 1px solid black;">Signature of Authorized Officer</td> </tr> <tr> <td style="border-bottom: 1px solid black;">ISA/U.S.</td> <td style="border-bottom: 1px solid black;">Mark S. Graham <i>[Signature]</i></td> </tr> </table>			Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	15 November 1988	03 FEB 1989	International Searching Authority	Signature of Authorized Officer	ISA/U.S.	Mark S. Graham <i>[Signature]</i>							
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report																
15 November 1988	03 FEB 1989																
International Searching Authority	Signature of Authorized Officer																
ISA/U.S.	Mark S. Graham <i>[Signature]</i>																

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☒ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers _____, because they relate to subject matter ¹² not required to be searched by this Authority, namely:

2. ☒ Claim numbers 8, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out ¹³, specifically:

No Claim 8 was filed.

3. ☐ Claim numbers _____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ²

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.